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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant Claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 330.00

Complete if Known	
Application Number	09/996,505
Filing Date	November 28, 2001
First Named Inventor	Raymond J. Wong
Examiner Name	Krishnan S. Menon
Art Unit	1723
Attorney Docket No.	3192-002

OIPE JC34 JUL 0 2 2004 PATENT & TRADEMARK

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☒ Credit card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account

Deposit Account Number: 50-0925

Deposit Account Name: Kilyk & Bowersox, P.L.L.C.

The Director is authorized to: *(check all that apply)*

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims	-20**=		X		=	
Independent Claims	- 3**=		X		=	
Multiple Dependent					=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

** *or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge – late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	330.00
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive – unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 330.00

SUBMITTED BY

Complete *(if applicable)*

Name (Print/Type)	Luke A. Kilyk	Registration No. (Attorney/Agent)	33,251	Telephone	1-540-428-1701
Signature				Date	July 2, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** *If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

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Donald S. Prater _____
Name (Print) Signature

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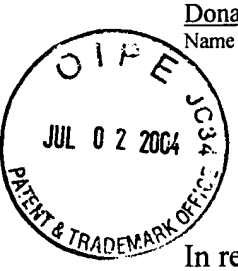
Donald S. Prater — Donald S. Prater
Name of Person signing Certificate — Signature



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Raymond J. Wong	)	Examiner: Krishnan S. Menon
Application No.: 09/996,505	)	Group Art Unit: 1723
Filed: November 28, 2001	)	Confirmation No.: 2941
Docket No.: 3192-002	)	Customer No.: 33432

For: CARTRIDGES USEFUL IN CLEANING DIALYSIS SOLUTIONS

SUBMISSION OF APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

July 2, 2004

Sir:

Submitted herewith are an original and two copies of an Appeal Brief in the above-identified U.S. patent application.

Also enclosed is a Credit Card Payment form in the amount of $330.00 to cover the cost of filing this Appeal Brief. In the event that any additional fees are due with respect to this paper, please charge Deposit Account No. 50-0925. This paper is filed in triplicate.

Respectfully submitted,

KILYK & BOWERSOX, P.L.L.C.

Luke A. Kilyk
Reg. No. 33,251

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Date: July 2, 2004 Label No. EV369584914US
I hereby certify that, on the date indicated above, I deposited this paper with identified attachments and/or fee with the U.S. Postal Service and that it was addressed for delivery to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 by "Express Mail Post Office to Addressee" service.

Donald S. Prater — Donald S. Prater
Name of Person signing Certificate — Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Raymond J. Wong	)	Examiner: Krishnan S. Menon
Application No.: 09/996,505	)	Group Art Unit: 1723
Filed: November 28, 2001	)	Confirmation No.: 2941
Docket No.: 3192-002	)	Customer No.: 33432

For: CARTRIDGES USEFUL IN CLEANING DIALYSIS SOLUTIONS

APPELLANT'S BRIEF ON APPEAL

July 2, 2004

Sir:

This is an appeal to the Board of Patent Appeals and Interferences (hereinafter "the Board") from the Examiner's December 3, 2003 final rejection of claims 1-11, 13-38, and 50-61 in the above-identified application. Claims 40, 42-46, 48, and 49 are withdrawn. No serious burden exists to examine all of the claims at this time. Furthermore, while claims 40, 42-46, 48, and 49 are withdrawn, the appellant believes that with the allowance of the independent claims, these claims should be allowable as well since they relate to method claims that are using the sorbent cartridge of the independent claims that have been examined. The appealed claims and the rest of the pending claims are set forth in the attached Appendix.

I. THE REAL PARTIES IN INTEREST

The real party in interest, besides the named inventor, is Renal Solutions, Inc.

II. RELATED APPEALS AND INTERFERENCES

No other appeal or interference which would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal is known to the appellant or the appellant's legal representative.

III. STATUS OF CLAIMS

The claims pending in the application are claims 1-11, 13-38, 40, 42-46, and 48-61. Claims 12, 39, 41, and 47 are canceled.

Claims 40, 42-46, 48, and 49 were withdrawn due to a restriction requirement. However, in a final Office Action dated December 3, 2003, the Examiner indicated that claims 40, 42-46, 48, and 49 would be allowable if the product claims are found allowable.

A copy of the claims on appeal and the rest of the pending claims can be found in the attached Appendix.

IV. STATUS OF AMENDMENTS

In response to the final Office Action dated December 3, 2003, a Request for Reconsideration dated May 3, 2004, was filed. No amendments were made. An Advisory Action dated May 26, 2004 was received.

V. SUMMARY OF INVENTION

There is always a continuing effort to improve cartridges useful in cleaning dialysis solutions. Prior to the present invention, the REDY cartridge was used for certain dialysis therapy. While this cartridge had a good efficacy and safety record, the REDY cartridge can produce a variation of dialysate composition and pH during the treatment with a continuous release of Na^+ by the cartridge. Thus, the REDY dialysis therapy had to provide several dialysate prescriptions to balance the Na^+ level in the patient for the correction of hyper and hyponatremia. The current method of making ZrP for the REDY cartridge is titrating acid ZrP (H^+ZrP) to the pH range 6.25 - 6.45 in a NaCl/NaAc buffer to produce Na^+H^+ZrP with high Na^+ content. This will trigger the Na^+ release especially in acetate or lactate dialysate with low buffer capacity and at low pH. Thus the ZrP quality made for the REDY cartridge may not be suitable for the peritoneal dialysis (PD) fluid regeneration application. (*See* pages 6 and 7 of the present application). Another disadvantage of using the previously designed REDY cartridge for PD treatment is that it may produce a continuous rise of Na^+ concentration of up to 170 mEq/l due to dominate Na^+ exchange throughout the treatment. In addition, an initial dip of Na^+, HCO_3, and pH may occur due to short time H^+ exchange. (*See* page 8, lines 6-10 of the present application).

The claimed invention contains a number of features that are listed at page 8, line 17 - page 9, line 9, that are useful in the regeneration or purification of solutions containing waste products in dialysis solutions. Preferably, the solutions are dialysis solutions such as peritoneal dialysis solutions, or other dialysate solutions such as those used in hemodialysis.

The present invention relates to a sorbent cartridge that contains at least sodium zirconium carbonate (SZC). In many embodiments, the sorbent cartridge is designed to have

layers of various materials, as shown, for instance, in Figure 4 of the present application. In a preferred embodiment, the SZC is present in at least one layer in a sorbent cartridge. In another preferred embodiment, zirconium phosphate (ZrP) is additionally present. The characteristics of the SZC of the claimed invention are described, for instance, in detail at page 12, lines 15-23, of the present application.

The ZrP embodiment of the present invention preferably includes characteristics that are described, for instance, in detail at page 14, lines 18 - page 15, line 2, of the present application.

The present invention further relates to a sorbent cartridge that contains at least sodium-Group IV B metal carbonate or other alkali metal-Group IV B metal carbonate. The alkali metal-Group IV metal carbonate is preferably present as a layer in the sorbent cartridge. Furthermore, a Group IV B metal phosphate can additionally be present in the sorbent cartridge. *See*, for instance, page 9, lines 11-15, of the present application.

Examples of Group IV B metal carbonates are described at page 11, lines 19-23, of the present application, which include titanium, zirconium, and hafnium.

In one or more embodiments, the present invention further provides a sorbent cartridge having an SZC layer, a ZrP, alumina, alumina supported urease, and granular activated carbon. According to page 22, lines 21-25, of the present application, preferably, one or more filter pads can be located throughout the sorbent cartridge to ensure that the integrity of the layers is maintained during operation.

VI. ISSUES

The issues remaining for review by the Board of Patent Appeals and Interferences are:

A. The Examiner's rejection of claims 1-9, 11, 13-16, 19-25, 29-38, and 50-61 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. (U.S. Patent No. 4,650,587) in view of the "Applicant's own disclosure of prior art" of the REDY cartridge.

B. The Examiner's rejection of claims 26-28 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the "Applicant's own disclosure of prior art" of the REDY cartridge, and further in view of Potts (U.S. Patent No. 5,234,603).

C. The Examiner's rejection of claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the "Applicant's own disclosure of prior art" of the REDY cartridge, and further in view of Marantz et al. (U.S. Patent No. 3,669,880).

D. The Examiner's rejection of claim 10 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the "Applicant's own disclosure of prior art" of the REDY cartridge, and further in view of Tawil et al. (U.S. Patent No. 4,025,608).

VII. GROUPING OF THE CLAIMS

As presently appealed, the groupings of the claims are as follows.

Claims 1, 11, 14, 15, 20, 37, 38, and 50-57 stand or fall together;

Claim 2 stands or falls on its own;

Claims 3, 5-10, 13, 30, 31, and 58-61 stand or fall together;

Claim 4 stands or falls on its own;

Claim 16-18 stand or fall together;

Claim 19 stands or falls on its own;

Claim 21 stands or falls on its own;

Claims 22-25 stand or fall together;

Claims 26-28 stand or fall together;

Claim 29 stands or falls on its own; and

Claims 32-36 stand or fall together.

VIII. ARGUMENTS

A. The Examiner's rejection of claims 1-9, 11, 13-16, 19-25, 29-38, and 50-61 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. (U.S. Patent No. 4,650,587) in view of the "Applicant's own disclosure of prior art" (the REDY cartridge).

1. The Examiner's rejection.

At page 2 of the final Office Action, the Examiner rejects claims 1-9, 11, 13-16, 19-25, 29-38, and 50-61 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the appellant's own disclosure of the REDY cartridge. According to the Examiner, Polak et al. describes a sorbent comprising at least one SZC as recited in claims 1 and 11 of the present application. The Examiner indicates that Polak et al. describes a capsule, and not layers, comprising an SZC. However, the Examiner asserts that the appellant's disclosure of the REDY cartridge describes sorbents configured as layers in a cartridge. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time of invention, to use the teachings of the REDY cartridge in Polak et al.

At page 9 of the Office Action, the Examiner responds to the Amendment dated October 15, 2003. According to the Examiner, in the Amendment dated October 15, 2003, the appellant argued that Polak et al. does not teach or suggest using a layered structure and never once taught ZrP with SZC. In response, the Examiner states that Polak et al. describes ZrP as prior art. Furthermore, the Examiner states that Polak et al. does not teach away from ZrP. According to the Examiner, magnesium phosphate (MGP) product is taught as an alternative or improvement over ZrP. Furthermore, the Examiner states that having the material in a pouch does not make it any less layered.

The Examiner also states that the fact that the appellant has recognized another advantage, which would flow naturally from following the suggestion of the prior art, cannot be the basis for patentability when the differences would otherwise be obvious. Furthermore, the Examiner emphasizes that Polak et al. describes a layered structure by the myriads of references cited therein, which, according to the Examiner, show a layered structure.

For the following reasons, the Examiner's rejection should be reversed.

2. The Appellant's Reply to the Examiner's rejection of claims 1-9, 11, 13-16, 19-25, 29-38, and 50-61 under 35 U.S.C. §103(a) as being over Polak et al. (U.S. Patent No. 4,650,587) in view of the "Applicant's own disclosure of prior art" (the REDY cartridge).

Throughout the final Office Action, the Examiner refers to "applicant's own disclosure of prior art." In reviewing the rejections, the Examiner is specifically referring to "applicant's disclosure of prior art REDY® teaches sorbents in layers in a cartridge (Specification, pages 5-8, and Figures 1 and 8)." *See* page 3 of the final Office Action. The applicant provided to the Examiner by way of an Information Disclosure Statement two detailed booklets to the Examiner

entitled "Guide to Custom Dialysis," and entitled "Sorbent Dialysis Primer," which both are dated 1993 and set forth the configuration of the REDY cartridge. Most importantly, as shown in these booklets, this chemical field is very complex. Reference throughout this Appeal Brief to the "REDY cartridge" is with reference to the REDY cartridge as set forth in these booklets, as well as Figures 1 and 8 in the present application.

a) The patentability of claims 1, 11, 14, 15, 20, 37, 38, and 50-57.

In terms of the claims at issue, the following summary is provided:

Claim 1 recites a sorbent cartridge comprising at least two layers, wherein one of the layers comprises at least sodium zirconium carbonate in the sorbent cartridge.

Claim 11 recites a sorbent cartridge comprising an alkali metal-Group IV B metal carbonate, wherein the alkali metal-Group IV B metal carbonate is present as a layer in the sorbent cartridge.

Claim 14 is dependent on claim 1 and recites that the sorbent cartridge further includes alumina, alumina supported urease, granular activated carbon, or combinations thereof. Claim 15 recites that the alumina, alumina supported urease, and granular activated carbon of claim 14 are each present as separate layers in the sorbent cartridge.

Claim 20 is dependent on claim 1 and recites that the sodium zirconium carbonate satisfies the ANSI/AAMI RD-5-1992 standard on extractable toxic impurities.

Claim 37 is dependent on claim 11 and recites that the sorbent cartridge further comprises a chlorine removal material.

Claim 38 is dependent on claim 11 and recites that the materials are present as two or more layers in said cartridge.

Claim 50 recites an apparatus for conducting dialysis comprising the sorbent cartridge of claim 1 and a dialyzer in fluid communication with the cartridge wherein spent dialysis fluid passes from the dialyzer to and through the cartridge.

Claim 51 is dependent on claim 50 and recites that the spent dialysis fluid is spent hemodialysis fluid.

Claims 52 and 57 are dependent on claims 50 and 1, respectively, and recite that the spent dialysis fluid is restored to the original balance of the Na^+ and HCO_3^- contents found in a fresh dialysate, and that the cartridge is capable of restoring the balance of Na^+ and HCO_3^- in spent dialysate to levels found in a fresh dialysate, respectively.

Claim 53 is dependent on claim 50 and recites that the dialyzer is in fluid communication with the blood of a patient.

Claim 54 is dependent on claim 53 and recites that the Na^+ and HCO_3^- balance in the blood is restored to levels found in a healthy patient without renal problems.

Claim 55 is dependent on claim 50 and recites that the spent dialysis fluid is spent dialysate fluid obtained from a dialyzer wherein spent peritoneal dialysis fluid is passed through the dialyzer and cleaned by fresh dialysate fluid.

Claim 56 recites a dialysis system including a sorbent cartridge and a source of spent peritoneal dialysis solution, wherein the source of the spent peritoneal dialysis solution is in fluid communication with the cartridge and wherein the spent peritoneal dialysis solution passes to and through the cartridge.

With respect to claims 1 and 11, Polak et al. relates to a particulate magnesium phosphate product (MGP) and to a method for removing ammonia from aqueous solutions. According to

Polak et al., MGP can be utilized as a replacement for ZrP materials, which are used to remove ammonia produced by enzymatic hydrolysis of urea in recirculating dialysis systems utilizing disposable cartridges.

Polak et al. does not teach or suggest that the SZC is present as a layer in a sorbent cartridge. SZC is never used alone in Polak et al. Polak et al. requires that SZC be used with MGP. For example, Polak et al. at Figure 2 and column 6, lines 9-11, only describes a mixture of MGP and SZC components in a pouch. There is absolutely no teaching or even a suggestion to use SZC as a layer with other layered materials. A mixture of MGP and SZC in a pouch does not constitute a layer in a cartridge and most certainly does not constitute a SZC layer. Therefore, contrary to the Examiner's statements, Polak et al. does not teach or suggest using a layered structure and never once teaches ZrP with SZC.

Further, the use of a layer of SZC has an important function, and is not a cosmetic difference. In one example of the present application, the SZC layer is, in part, a phosphate adsorbent, which can remove phosphate from a renal disease patient for the treatment of hyperphosphatemia. Preferably, SZC produces bicarbonates that can be delivered to a patient for correcting the metabolic acidosis. Furthermore, the SZC layer, preferably, buffers the acidity of the dialysate caused by the lattice hydrogen ions of ZrP and hydrous zirconium oxide (HZO), which will otherwise decompose the bicarbonate dialysate and lower the bicarbonate level of the patient.

With respect to the Examiner's argument that having the material in a pouch does not make it any less layered, at page 3 of the Office Action the Examiner specifically states that Polak et al. does not disclose layers comprising SZC. Further, claim 1 of the present application specifically

recites two layers, one of which is SZC. Where are the two layers in Polak et al.? Polak does not show two layers at all. Certainly, the Examiner cannot point to any part of Polak et al to support the Examiner's position. The Examiner, at page 5 of the final Office Action, further emphasizes that Polak et al. does not describe layers comprising SZC by stating that Polak et al. does not teach how the absorbents are structured in the cartridge.

With respect to the REDY cartridge, as shown in Figures 1 and 8 of the present application, and as further shown in the booklets, "Guide to Custom Dialysis" and "Sorbent Dialysis Primer," the REDY cartridge is a cartridge having a very specific arrangement of chemical layers. As shown in Figure 1 of the present application, the REDY cartridge does not include any layer which contains sodium zirconium carbonate.

Furthermore, the REDY cartridge includes layers, whereas the cartridge of Polak et al. does not. How the REDY cartridge can be combinable with Polak et al. is not seen.

Further, one cannot simply replace one of the layers in the REDY cartridge with the material of Polak et al. and reasonably expect success. At best, this is an improper obvious to try standard.

The Examiner cannot simply pick and choose layers and design a cartridge to reject the claimed invention when the prior art does not provide this motivation. The Examiner is improperly using hindsight to arrive at this conclusion. The REDY cartridge disclosure and Polak et al. do not suggest such a substitution

With respect to claims 14, 15, 37, and 38, simply because a similar general material may be mentioned in a reference does not mean that the compound has the same properties. There has to be a technical basis for concluding obviousness or for asserting inherency. It is not enough for the

Examiner to simply say that the same material is automatically used when clearly the present invention, especially the claims of the present invention, set forth precise chemical properties or amounts which clearly are not taught or suggested in the cited art. The Examiner at times asserts that certain characteristics are "a material property," and therefore concludes obviousness. However, a material property that is not taught or suggested in the cited art is clearly reason enough for patentability. There are many patents that would attest to this standard.

In addition, with respect to claim 20, wherein the Examiner states that the material of Polak et al. would satisfy the ANSI/AAMI standard, again, the Examiner has not even shown that the material is the same and therefore, one cannot conclude that it would satisfy such a requirement. This is especially true when the material used in Polak et al. is not even used as a layered structure.

With respect to the Examiner's rejection of claim 29, wherein the Examiner asserts that the "[d]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art," first of all, the appellant respectfully points out that the claims being rejected are product claims and not process claims. Thus, the Examiner's argument does not apply. In addition, the sorbent cartridge claims are not "a known process" or a known product. As pointed out above, clearly Polak et al. does not teach or suggest these amounts which are present in a layered structure. Since the purpose and design of Polak et al. is not even close to the claimed invention, one cannot assert that this is a mere optimization issue. Clearly, these amounts have relevance as shown in the present application and the relevance of these amounts are clearly not taught or suggested in Polak et al. or by the REDY cartridge.

Accordingly, for the reasons stated above, Polak et al., in view of the REDY cartridge, does not render the claimed invention unpatentable, and the rejection of claims 1, 11, 14, 15, 20, 37, 38, and 50-57 should be reversed.

b) The patentability of claim 2.

Claim 2 is dependent on claim 1 and recites that the sodium zirconium carbonate is present as a layer in the sorbent cartridge wherein one of the layers consists essentially of sodium zirconium carbonate.

As the Board is well aware, the language "consisting essentially of" is an introductory term used in patent claims, which commonly follows the claim preamble and introduces the elements making up the claim. The use of the term "consisting essentially of" to introduce the elements of a claim leaves the claim open only for the inclusion of other components, ingredients, or process steps that do not materially affect the basic and novel characteristics of the invention.

As stated above, claim 2 recites that one of the layers consists essentially of SZC, which means that one of the layers includes SZC and other components or ingredients that do not materially affect the basic and novel characteristics of the layer.

As stated above, Polak et al. does not teach or suggest that the SZC is present as a layer in a sorbent cartridge. SZC is never used alone in Polak et al. Polak et al. requires that SZC be used with MGP. *See* Figure 2 and column 6, lines 9-11. Polak et al. only describes a mixture of MGP and SZC components in a pouch. Given that MGP is a critical ingredient and the primary ingredient of Polak et al., Polak et al. does not teach or suggest a layer that consists essentially of sodium zirconium carbonate.

The REDY cartridge includes layers; however, none of the layers in the REDY cartridge

includes an SZC. Furthermore, there is no teaching, suggestion, or motivation to separate the mixture of the MGP and SZC, in order to form SZC alone into a layer, and then to replace one of the layers of the REDY cartridge with the formed SZC layer.

Accordingly, for the reasons stated above, Polak et al., in view of the REDY cartridge, does not render the claimed invention unpatentable, and the rejection of claim 2 should be reversed.

c) The patentability of claims 3, 5-9, 13, 30, 31, and 58-61.

Claim 3 is dependent on claim 1 and recites that the sorbent cartridge further includes a zirconium phosphate.

Claim 5 is dependent on claim 3 and recites that the zirconium phosphate comprises a H^+ content of from about 1.4 to about 2.0 wt%; a Na^+ content of from about 4 to about 6 wt%; a ZrO_2 wt% of from about 34 wt% to about 37 wt%; a PO_4 wt% of from about 41 wt% to about 43 wt%; and a H_2O wt% of from about 14 wt% to about 18 wt%, based on the weight of the zirconium phosphate.

Claim 6 is dependent on claim 3 and recites that the zirconium phosphate has at least one of the following characteristics: (a) an adsorption capacity for ammonia of from about 20 mg NH_4-N/gm ZrP to about 45 mg NH_4-N/gm ZrP; an adsorption capacity for Ca^{2+} of from about 2 mEq Ca^{2+}/gm ZrP to about 7 mEq Ca^{2+}/gm ZrP; an adsorption capacity for Mg^{2+} of from about 1 mEq Mg^{2+}/gm ZrP to about 5 mEq Mg^{2+}/gm ZrP; and an adsorption capacity for toxic heavy metals of from about 3 mEq HM/gm ZrP to about 9 mEq HM/gm ZrP; (b) a Na^+ content of from about 1.8 mEq Na^+/gm ZrP to about 3 mEq Na^+/gm ZrP at a pH of from about 5.5 to about 6; (c) a minimum leachable PO_4^{3-} of less than about 0.05 mg PO_4^{3-}/gm ZrP; or (d) satisfying ANSI/AAMI RD-5-1992 standard on extractable toxic impurities.

Claims 7 and 8 are dependent on claim 5, and claim 9 is dependent on claim 3, and recite that the zirconium phosphate has no residual sulfate or chloride; has less than 0.01% sulfate, chloride, or both; and has a pH of from about 6 to about 7, respectively.

Claim 13 is dependent on claim 11 and recites that the sorbent cartridge further includes a Group IV B metal phosphate.

Claim 30 is dependent on claim 29 and recites that the cartridge further includes zirconium phosphate in an amount of from about 300 grams to about 1900 grams.

Claim 31 is dependent on claim 30 and recites that the cartridge further includes alumina in the amount of from about 100 grams to about 500 grams, immobilized enzyme in an amount of from about 100 grams to about 300 grams, and activated carbon or other adsorbent in an amount of from about 100 grams to about 500 grams.

Claims 58 and 59 are dependent on claims 5 and 31, respectively, and recite that the cartridge is capable of restoring the balance of Na^+ and HCO_3^- in spent dialysate to levels found in fresh dialysate, and that the cartridge is capable of restoring the balance of Na^+ and HCO_3^- in spent dialysate to levels found in fresh dialysate, respectively.

Claims 60 and 61 are dependent on claims 3 and 4, respectively, and recite that the zirconium phosphate is further away from an inlet opening of the sorbent cartridge than the layer of sodium carbonate and SZC, respectively.

Polak et al. does not teach or suggest using a layered structure, and never once teaches or suggests the use of ZrP with SZC. Columns 5 and 6 of Polak et al., which the Examiner relies upon, only show the use of MGP mixed with SZC.

Polak et al. uses MGP with an SZC and discourages the use of ZrP. Polak et al. specially

teaches that MGP is a replacement for ZrP. There is absolutely no teaching or suggestion in Polak et al. to use ZrP with SZC, especially in any layered configuration.

The layered structure of the claimed invention is based on the principle of adsorption column design to ensure high adsorption efficiency. A blended mixture of components, especially a blended mixture of ZrP and SZC, will not only cause a high level of phosphate leakage, but also can cause a rapid uncontrolled reaction that produces CO_2 gas during application.

Although the references cited in Polak et al., such as U.S. Patent No. 3,669,880, describe a cartridge having a ZrP layer, the references simply do not teach or suggest the use of an SZC layer in combination with a ZrP layer. As stated above, Polak et al. even discourages the use of ZrP due to its disadvantages as mentioned at col. 3, lines 11-36; and col. 4, lines 38-48, and the references cited within Polak et al. Polak et al. further states that MGP is a replacement for ZrP. One skilled in the art would conclude that SZC can only be used in combination with MGP and not with ZrP. In addition, none of the references in Polak et al. shows the use of SZC as a layer.

Furthermore, the REDY cartridge, as stated above, relates to several layers of chemical materials. One of these layers is zirconium phosphate. There is no sodium zirconium carbonate layer in the REDY cartridge. The Examiner does not dispute this point. If one combines Polak et al. with the REDY cartridge, if this is possible, at best one skilled in the art would substitute the zirconium phosphate layer of the REDY cartridge, for instance, as shown in Figure 1 of the present application, with the magnesium phosphate product of Polak et al. As stated, Polak et al. specifically states that the magnesium phosphate product of Polak et al. is a replacement for zirconium phosphate. Thus, if one combines Polak et al. with the REDY cartridge, one would

replace the zirconium phosphate layer of the REDY cartridge with the magnesium phosphate product of Polak et al. which may contain sodium zirconium carbonate. If this is done, then by this combination, the REDY cartridge would not have any zirconium phosphate layer since it was replaced with the magnesium phosphate product of Polak et al. based on the Examiner's reasoning. Therefore, with this combination, the REDY cartridge would no longer have any zirconium phosphate layer since it was replaced with the magnesium phosphate product of Polak et al. In view of this, the REDY cartridge, even combined with Polak et al., cannot possibly suggest a sorbent cartridge that contains both zirconium phosphate along with sodium zirconium carbonate as required by claim 3. After all, the zirconium phosphate was replaced by the magnesium phosphate product of Polak et al. which may contain sodium zirconium carbonate. There are no exceptions to this replacement made in Polak et al. or in the patents referenced by Polak et al. The magnesium phosphate product of Polak et al. is an absolute replacement for the zirconium phosphate.

Additionally, one skilled in the art, after reviewing the teachings of Polak et al. and the REDY cartridge, would not be motivated to replace the HZO layer of the REDY cartridge with SZC. Neither Polak et al. nor the REDY cartridge teaches or suggests such a substitution. Where is the suggestion in the cited references? In fact, based on the high level of phosphate leakage created by having a blended mixture of ZrP and SZC, one skilled in the art would prefer to use HZO instead of SZC.

With respect to the Examiner's rejection of claims 5, 6, 7, 8, 9, and 30 and the remaining rejected claims, clearly Polak et al. does not teach or suggest these amounts or other characteristics which are present in a layered structure. Since the purpose and design of Polak et al. is not even close to the claimed invention, one cannot assert that this is a mere optimization issue. Clearly,

these amounts have relevance as shown in the present application and the relevance of these amounts are clearly not taught or suggested in Polak et al. or by the Examiner's reliance on the REDY cartridge.

Accordingly, for the reasons stated above, Polak et al., in view of the REDY cartridge, does not render the claimed invention unpatentable and the rejection of claims 3, 5-9, 13, 30, 31, and 58-61 should be reversed.

d) The patentability of claim 4.

Claim 4 recites that the zirconium phosphate of claim 3 is present as a layer in the sorbent cartridge.

With respect to claim 4, which recites that the zirconium phosphate is present as a layer in the sorbent cartridge along with a separate layer of sodium zirconium carbonate, again, Polak et al. specifically states that the magnesium phosphate product of Polak et al. is a full replacement for zirconium phosphate. Therefore, if one somehow combined Polak et al with the REDY cartridge, for instance, as shown in Figure 1 of the present application, one would replace the zirconium phosphate layer of the REDY cartridge with the magnesium phosphate product of Polak et al. Thus, after this combination, there would be absolutely no zirconium phosphate layer present in the REDY cartridge. Therefore, claim 4 cannot possibly be obvious in view of this combination since claim 4 requires a zirconium phosphate layer and a sodium zirconium carbonate layer in the same sorbent cartridge.

Clearly, this rejection should be reversed as well.

e) The patentability of claim 16.

Claim 16 is dependent on claim 15 and recites that the layers have the following order: a)

a sodium zirconium carbonate; b) a zirconium phosphate; c) alumina; d) an alumina supported urease; and e) granular activated carbon.

Claim 16 recites a specific order of layers which clearly is not taught or suggested in the cited references as admitted by the Examiner. It is important for the Board to recognize that the scope of the invention is determined by the language recited in the claims and not by the options provided in the specification. The Examiner cannot use the appellant's own disclosure for purposes of rejecting the claims. Furthermore, in addition to not teaching or suggesting the particular order of the layers present as recited in claim 16 of the present application, the REDY cartridge does not teach or suggest an SZC layer as taught by claim 16 of the present application. Additionally, as stated above, Polak et al. does not teach or suggest a cartridge having layers. Furthermore, no motivation exists to separate the MGP and SZC mixture of Polak et al., to form the separated SZC into a layer, and to substitute one layer of the REDY cartridge with the formed SZC layer. Also, as indicated above, if Polak et al. is combined with the REDY cartridge, then the magnesium phosphate product of Polak et al. will replace the ZrP layer of the REDY cartridge, and result in no ZrP layer at all. Claim 16 requires a ZrP layer and a separate SZC layer.

With respect to the Examiner's reliance on *In re Gazda*, 104 U.S.P.Q. 400 (C.C.P.A. 1955), *In re Japikse*, 86 U.S.P.Q. 70 (C.C.P.A. 1950), and *In re Kuhle*, 188 U.S.P.Q. 7 (C.C.P.A. 1975), the appellant responds as follows. The Examiner relied on these decisions to argue that the mere shuffling of the positions of parts to produce a new product, when there is no particular advantage, would not be patentable over the prior art. However, these cases are not analogous to the present invention. First, each of these decisions related to mechanical devices and not chemical inventions. The re-arrangement of mechanical parts is quite a different issue than how

chemical layers are arranged. In addition, as explained above, even the art combined does not show the claimed invention, even after the Examiner's use of hindsight.

For instance, *In re Gazda* related to a clock on a steering wheel and the C.C.P.A. clearly stated that there was an abundant suggestion in the prior art for modification of the structures of the references to arrive at the appellant's device. Unlike *In re Gazda*, the Examiner has not shown a single reference that shows sodium zirconium carbonate as a layer amongst other layers in a sorbent cartridge. Moreover, as set forth in claim 16, there are five layers recited in claim 16 in a particular order and the Examiner has not shown any prior art alone or combined with other prior art that teaches or suggests these layers in this particular order. In fact, the Examiner improperly refers to the specification of the present application to assert that any order can be used. However, the teachings set forth in the present application are not prior art and cannot be used as "an admission" as asserted by the Examiner, for instance, in paragraph 6 of the Advisory Action. The Examiner's reliance on the applicant's own specification to reject a claim is clearly legally incorrect. Claim 16 recites a precise order of layers and the Examiner never once sets forth how the prior art would teach or suggest this particular arrangement. In addition, this particular layer arrangement as shown in the present application results in an effective way to provide a method to regenerate or purify spent dialysis fluid. The Examiner attempts to trivialize the chemistry that is set forth in this invention when, in fact, the layer arrangement and the types of materials used in each layer lead to an effective way to provide a means to regenerate or purify spent dialysis fluid.

In addition, the Examiner relies on legal decisions regarding purely mechanical inventions and the location of mechanical parts. The Examiner apparently takes the position that

the present invention involves merely a form of mechanical layers that can be interchanged as various mechanical parts as set forth in the case law relied upon by the Examiner. To the contrary, the present invention relates to a complicated chemical sorbent cartridge which involves layers that contain various chemical materials which can affect each other. These layers, for instance, recited in claim 16, are not merely mechanical parts. The present invention is a chemical invention that involves the use of various chemical layers that, in a certain order, can provide various benefits as explained in the present application to regenerate or purify spent dialysis fluid. Each of the cases relied upon by the Examiner relate to a purely mechanical invention wherein the invention was found obvious in view of the cited prior art in that a mechanical part was simply located in a different location. Unfortunately, the Examiner ignores the chemistry of the present application and simply believes that it would be proper to randomly pick and choose and re-arrange various layers to come up with the claimed invention when the prior art does not provide any motivation to make these substitutions, and the prior art does not teach or suggest that one would reasonably expect success in making such substitutions.

Accordingly, for the reasons stated above, Polak et al., in view of the REDY cartridge does not render the claimed invention unpatentable, and the rejection of claim 16 should be reversed.

f) The patentability of claim 19.

Claim 19 is dependent on claim 1 and recites that the sodium zirconium carbonate comprises from about 2 wt% to about 5 wt% Na^+; from about 44 wt% to about 50 wt% ZrO_2; from about 12 wt% to about 18 wt% CO_3^{2-}; and from about 30 wt% to about 40 wt% LOD, based on the weight of the sodium zirconium carbonate.

With respect to claim 19, the appellant respectfully points out that the SZC product set forth in Polak et al., as described at the top of column 6, has the formula $Na_{0.8\text{-}1.2}(ZrO_2)_1(CO_3)_{0.8\text{-}1.2}$.

On the other hand, this formula clearly would not be covered, for instance, by the SZC set forth in claim 19 of the present application.

Accordingly, for the reasons stated above, including the reasons set forth above with respect to claim 1, Polak et al., in view of the REDY cartridge does not render the claimed invention unpatentable, and the rejection of claim 19 should be reversed.

g) The patentability of claim 21.

Claim 21 is dependent on claim 1 and recites that the sodium zirconium carbonate satisfies at least one of the following characteristics: a phosphate adsorption having a minimum capacity of from about 30 to about 35 mg/PO_4-P/gm SZC; a minimum HCO_3^- content of from about 2 to about 4 mEq HCO_3^- per gm SZC; a leachable Na^+ content of from about 1.5 to about 2.0 mEq Na^+/gm SZC; or a pH range of titrated sodium zirconium carbonate of from about 6 to about 7.

With respect to claim 21 and the rejection, Polak et al. does not teach or suggest the characteristics of the sodium zirconium carbonate as recited in claim 21. The characteristics as set forth in claim 21 lead to an effective and sufficient way to regenerate or purify spent dialysis fluid. Polak et al. does not provide any such characteristics and would not even appreciate the need for these characteristics since, as stated above, the importance of Polak et al. relates to magnesium phosphate and Polak et al. simply uses sodium zirconium carbonate as an extra component to mix with the magnesium phosphate. Polak et al. is not interested in using sodium zirconium carbonate in the same manner as set forth in the sorbent cartridge of the present

invention and therefore would not appreciate the characteristics useful in using sodium zirconium carbonate as a layer.

Furthermore, as discussed above, the REDY cartridge does not even teach or suggest the use of any sodium zirconium carbonate and therefore would not teach or suggest any characteristics of a sodium zirconium carbonate. Thus, even if Polak et al. is somehow combinable with the REDY cartridge, the subject matter of claim 21 is still not obvious in view of these references. The Examiner's rejection should be reversed.

h) The patentability of claims 22-25.

Claims 22 is dependent on claim 1 and recites that the sorbent cartridge further includes hydrous zirconium oxide and claim 23 recites that the hydrous zirconium oxide in claim 22 is in the acetate form.

Claim 24 is dependent on claim 23 and recites that the sodium zirconium carbonate and the hydrous zirconium oxide are present in a weight ratio of about 1 to 1.

Claim 25 is dependent on claim 23 and recites that the sodium zirconium carbonate and the hydrous zirconium oxide are present in the same layer and are blended together.

As stated earlier, one skilled in the art, after reviewing the teachings of Polak et al. and the REDY cartridge, would not be motivated to replace the HZO layer of the REDY cartridge with an SZC layer. Neither Polak et al. nor the REDY cartridge teach or suggest such a substitution. Furthermore, there is absolutely no motivation to add an SZC layer to the REDY cartridge or substitute the HZO layer of the REDY cartridge with an SZC layer. Additionally, even if one skilled in the art, as suggested by the Examiner, would substitute the HZO of the REDY cartridge with an SZC, such a substitution would still not teach or suggest claims 22-25 of the present

application. As recited in claims 22-25 of the present application, the sorbent cartridge of the claimed invention, in addition to the SZC, includes a HZO. Substituting one layer for the other, as the Examiner suggest, would not teach or suggest having both an SZC layer and an HZO layer.

Accordingly, for the reasons stated above, Polak et al., in view of the REDY cartridge, does not render the claimed invention unpatentable and the rejection of claims 22-25 should be reversed.

i) The patentability of claim 29

Claim 29 is dependent on claim 1 and recites that the sodium zirconium carbonate is present in the cartridge in an amount of from about 100 grams to about 300 grams. As stated above, Polak et al. specifically states that the magnesium phosphate is a replacement for zirconium phosphate. In addition, Polak et al. does state that a certain type of sodium zirconium carbonate can be used with the magnesium phosphate. However, other than a formula provided at column 6 of Polak et al., no other details are provided concerning the sodium zirconium carbonate. In fact, Polak et al. specifically states after indicating that a specific sodium zirconium carbonate product can be present "[h]owever, our primary interest is for the use of the MGP in a system to be ingested by uremic patients for the enteric elimination of urea." As stated, no other details concerning the amount of the sodium zirconium carbonate, and the like, are provided anywhere in Polak et al.

Claim 29, which is dependent on claim 1, recites a specific amount of the sodium zirconium carbonate that is present in a cartridge as a layer in the sorbent cartridge. As stated, first Polak et al. does not teach or suggest the use of any layer containing sodium zirconium carbonate alone or even with any other component. Second, Polak et al. does not describe any

amounts of the sodium zirconium carbonate. Moreover, the amounts specified in claim 29 of the present application would not be obvious or inherent in Polak et al. since the emphasis of Polak et al. is the magnesium phosphate product. Clearly, one skilled in the art reading Polak et al. alone or even combined with the REDY cartridge would not be able to find any teaching or even a suggestion on amounts of the sodium zirconium carbonate for use in a sorbent cartridge as a layer. Again, the Examiner has not established a prima facie case of obviousness with respect to this subject matter. Accordingly, the subject matter of claim 29 is not taught or suggested by Polak et al. or the REDY cartridge alone or combined.

j) The patentability of claims 32-36

Claim 32 recites a sorbent cartridge that is dependent on claim 1 and further comprises an immobilized enzyme material capable of enzymatic conversion of urea to ammonium carbonate, a cation exchange material in the sodium or hydrogen form, and anion exchange material in the Ac^-, HCO_3^-, Cl^-, or OH^- form, and an adsorbent capable of removing creatinine, uric acid, or both. Claim 33 is dependent on claim 32 and recites the additional presence of a chlorine removal material. Claim 34 is also dependent on claim 32 and recites that the materials are present as two or more layers in the cartridge. Claim 35 is dependent on claim 33 and recites that the materials are present as two or more layers in the cartridge.

Also, claim 36, which is dependent on claim 11, recites the same language as claim 32, but is, as indicated, dependent on claim 11.

Unlike the subject matter of these claims, Polak et al., as indicated, only shows a mixture of MGP with an SZC, nothing else. There are no layers taught or even suggested in Polak et al. Furthermore, the REDY cartridge does not teach a sorbent cartridge that has a sodium zirconium

carbonate layer or an alkali metal-Group IV-B metal carbonate layer in combination with the components recited in claims 32-36. The Examiner has not explained how one skilled in the art would simply take a sodium zirconium carbonate layer and include it in the REDY cartridge along with the other components recited in claims 32-36 and achieve any workable sorbent cartridge. Further, the ZrP layer of the REDY cartridge would be replaced by the MGP of Polak et al. as explained above, so the REDY cartridge would not have a cation exchange layer, since it was replaced by MGP. Certainly, Polak et al. does not teach or suggest that Polak et al.'s mixture of materials can be used with other sorbent materials in a layer form. Further, the REDY cartridge does not teach or suggest that any one layer can be substituted with a different chemical substance.

Accordingly, for the reasons stated above, one skilled in the art, even if somehow Polak et al. could be combined with the REDY cartridge, would still not consider claims 32-36 of the claimed invention obvious. Accordingly, the rejection of these claims should be reversed.

B. The Examiner's rejection of claims 26-28 under 35 U.S.C. § 103(a) as being unpatentable over Polak et al. in view of the "Applicant's own disclosure of prior art" of the REDY cartridge, and further in view of Potts (U.S. Patent No. 5,234,603).

1. The Examiner's rejection.

At page 7 of the final Office Action, the Examiner rejects claims 26-28 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge and further in view of Potts (U.S. Patent No. 5,234,603). The Examiner asserts that the REDY cartridge includes ZrO for purifying spent dialysate. Furthermore, the Examiner states that Potts describes a basic zirconium carbonate for removal of heavy metals, transition metals, and organic matter from

wastewater, and that zirconium carbonate would hydrolyze to form a polymeric oxide chain. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have the teachings of the REDY cartridge and Potts in the teaching of Polak et al. for purifying the spent dialysate as taught by Polak et al. In addition, the Examiner states that Potts, at col. 4, line 35, describes that the zirconium carbonate would hydrolyze to form a polymeric oxide chain.

At page 10 of the Office Action, the Examiner responds to the Amendment dated October 15, 2003. According to the Examiner, in the Amendment dated October 15, 2003, the appellant argued that Potts and Polak et al. are not within the same field of endeavor. In response, the Examiner states that the Zr compounds are considered ion exchange materials, as well as having use in dialysis, as taught by Polak et al. and Potts. Therefore, the Examiner concludes that Polak et al. and Potts are well within the field of the appellant's endeavor.

For the following reasons, the Examiner's rejection should be reversed.

2. The appellant's reply to the Examiner's rejection of claims 26-28 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge, and further in view of Potts (U.S. Patent No. 5,234,603).

a) The patentability of claims 26-28.

In terms of the claims at issue, the following summary is provided:

Claim 26 is dependent on claim 1 and recites that the sorbent cartridge further comprises zirconium basic carbonate.

Claim 27 is dependent on claim 26 and recites that the zirconium basic carbonate includes Na^+ of less than about 1000 ppm; a ZrO_2 wt% of from about 35 wt% to about 40 wt%;

and a CO_3^{2-} of from about 8 wt% to about 10 wt%, based on the weight of the zirconium basic carbonate.

Claim 28 is dependent on claim 27 and recites that the zirconium basic carbonate has about 0 wt% SO_4^{2-} and about 0 wt% Cl^-.

The arguments set forth above with respect to Polak et al. and the REDY cartridge apply equally here.

Further, Polak et al. relates to the preparation of MGP and its use in the medical field, its use in recirculating dialysis systems and other systems having the purpose of removing urea/ammonia from bodily fluids, and in wastewater treatment to remove ammonium ions. In contrast, according to Potts, at column 3, lines 55-61, the contaminants to be removed include actinide and lanthanide metals, transition metals, heavy metals, suspended solids (either organic, inorganic, and/or biological), alkaline earth metals, and similar insoluble materials (and materials which can be made insoluble) in the wastewater. Potts does not teach or suggest removal of urea or ammonia.

Furthermore, the zirconium carbonate in Potts is not used as an ion-exchange material to remove contaminants from wastewater. In fact, a reading of Potts indicates that its zirconium carbonate is used as a precipitating agent by itself or in combination with a coagulating agent, a reducing agent, or a weighting agent. Thus, the zirconium carbonate of Potts must be a soluble salt. Therefore, given that the zirconium carbonate of Potts is a soluble salt, it cannot form a layer in a sorbent cartridge. The two references are simply not within the same field of endeavor. Accordingly, one skilled in the art seeking to learn about the removal of urea/ammonia from bodily fluids would not look to Potts. The Examiner cannot use hindsight to mix and match the layers.

Absolutely no suggestion is made in either reference for mixing and matching the layers.

Accordingly, for the reasons stated above, Polak et al. in view of the REDY cartridge and Potts does not render the claimed invention unpatentable, and the rejection of claims 26-28 should be reversed.

C. The Examiner's rejection of claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the "Applicant's own disclosure of prior art" of the REDY cartridge, and further in view of Marantz et al. (U.S. Patent No. 3,669,880).

1. The Examiner's rejection.

At page 8 of the final Office Action, the Examiner rejects claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge, and further in view of Marantz et al. (U.S. Patent No. 3,669,880). According to the Examiner, claims 17 and 18 of the present application add structural components like filter pads and a diffuser. The Examiner then states that the REDY cartridge includes a filter pad (Fig. 1), but not the diffuser for flow distribution. However, the Examiner states that Marantz et al. describes a flow distributor and filter pads. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use the teaching of Marantz et al. in the teaching of Polak et al. in view of the REDY cartridge for the flow distribution and for preventing the breakup and inter-mixing of particles in layers as taught by Marantz et al. The Examiner further states that Marantz et al. is used to show a flow distributor and filter pads. Furthermore, at page 11 of the Office Action, the Examiner states that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references.

According to the Examiner, the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

For the following reasons, the Examiner's rejection should be reversed.

2. The appellant's reply to the Examiner's rejection of claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge, and further in view of Marantz et al. (U.S. Patent No. 3,669,880).

a) The patentability of claims 17 and 18.

In terms of the claims at issue, the following summary is provided:

Claim 17 is dependent on claim 16 and recites that the sorbent cartridge further comprises a first filter pad located above and in contact with the sodium zirconium carbonate, a second filter pad is located between and in contact with the alumina supported urease and the granular activated carbon, and a third filter pad is located beneath and in contact with the granular activated carbon.

Claim 18 is dependent on claim 17 and recites the sorbent cartridge further includes a flow diffuser located beneath and in contact with the third filter pad.

The arguments set forth above with respect to Polak et al. and the REDY cartridge apply equally here. As indicated, if Polak et al. teaches that magnesium phosphate replaces ZrP, then, when Polak et al. is combined with the REDY cartridge, there will no ZrP layer in the REDY cartridge since it has been replaced by magnesium phosphate.

Further, Marantz et al. relates to a recirculating dialysate system for use with an artificial kidney in which the total volume of dialysate solution is controlled. According to Marantz et al., the urea in the solution is removed in a ZrP column, and the other waste products are removed in the carbon column containing activated carbon and hydrated zirconium oxide. In contrast, Polak et al.

teaches away from Marantz et al. by replacing the ZrP with MGP. Thus, one skilled in the art, by reading Polak et al., would conclude that since the composition of Polak et al. is different from Marantz et al., the cartridge used in Marantz et al. would not work in Polak et al. Therefore, one skilled in the art would not be motivated to combine Polak et al. and Marantz et al.

Additionally, since the purpose of the flow distributor and filter pads of Marantz et al. are to prevent breakup and intermixing of particles in layers; and Polak et al. describes a pouch having intermixed particles of MGP and SZC, one skilled in the art would not look to Marantz et al. that describes a flow distributor and a filter to prevent intermixing of particles.

Furthermore, Marantz et al. has an issue date of June 13, 1972 and Polak et al. has an issue date of March 17, 1987. As indicated on the face page of Polak et al., the inventors of Polak et al. were well aware of Marantz et al. However the inventors of Polak et al. did not incorporate the fluid distributor and filter pads of Marantz et al. in Polak et al. Thus, clearly one of ordinary skill in the art would not have been motivated to combine the teachings of Polak et al. in view of the REDY cartridge with the teachings of Marantz et al.

Accordingly, for the reasons stated above, Polak et al. in view of the REDY cartridge and further in view of Marantz et al. does not render the claimed invention unpatentable and the rejection of claims 17 and 18 should be reversed.

D. The Examiner's rejection of claim 10 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the "Applicant's own disclosure of prior art" of the REDY cartridge, and further in view of Tawil et al. (U.S. Patent No. 4,025,608).

1. The Examiner's rejection.

At page 8 of the final Office Action, the Examiner rejects claim 10 under 35 U.S.C. §103(a)

as being unpatentable over Polak et al. in view of the REDY cartridge, and further in view of Tawil et al. (U.S. Patent No. 4,025,608). The Examiner asserts that ZrP has an average grain size of from about 30 to about 40 microns, which Polak et al. in view of the REDY cartridge does not teach. However, the Examiner states that Tawil et al. describes the particle size of the ZrP. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use the zirconium oxide particle size of Tawil et al. in the teaching of Polak et al. in view of the REDY cartridge for good flow distribution.

Furthermore, the Examiner states that ZrP made by any process would still be a ZrP unless the appellant can show a significant difference in the structure or the chemical composition of the product made by the different process.

For the following reasons, the Examiner's rejection should be reversed.

2. The Appellant's reply to the Examiner's rejection of claim 10 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge, and further in view of Tawil et al. (U.S. Patent No. 4,025,608).

a) The patentability of claim 10.

In terms of the claims at issue, the following summary is provided:

Claim 10 is dependent on claim 3 and recites that the zirconium phosphate has an average grain size of from about 30 to about 40 microns.

The arguments set forth above with respect to Polak et al. and the REDY cartridge apply equally here. As stated, if Polak et al. teaches that magnesium phosphate replaces ZrP, then, when Polak et al. is combined with the REDY cartridge, there will no ZrP layer in the REDY cartridge since it has been replaced by magnesium phosphate.

Further, Tawil et al. relates to a ZrP that is made by reacting a zirconium salt with a phosphoric acid or a phosphate in a liquid medium, wherein the zirconium salt is insoluble in water. The Examiner cannot simply substitute different particles and argue that the substituted particles automatically have the same size as the original particles. No support exists for such a conclusion. According to Tawil et al., at column 2, lines 54-59, the grain size of the ZrP is at least 30 microns. As discussed above, Polak et al. even teaches away from utilizing a ZrP. Thus, one skilled in the art, by reading Polak et al., would not be motivated to look to Tawil et al. for any guidance.

Furthermore, as stated earlier, one skilled in the art could not combine the teachings of Polak et al. with the REDY cartridge, and, even if combined, a mixture of various components, and not layers, would be used. Also, Polak et al. replaces ZrP with magnesium phosphate, and so if Polak et al. is combined with the REDY cartridge, no ZrP layer would exist, since the ZrP of the REDY cartridge is replaced by the magnesium phosphate of Polak et al. The Examiner cannot have it both ways. Therefore, one skilled in the art would not be motivated to combine Polak et al. with the REDY cartridge and Tawil et al. to derive claim 10 of the present application.

Accordingly, for the reasons stated above, Polak et al. in view of the REDY cartridge and further in view of Tawil et al. does not render the claimed invention unpatentable and the rejection of claim 10 should be reversed.

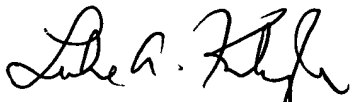
IX. CONCLUSION

For at least the reasons discussed above, it is respectfully submitted that the Examiner's rejection of all the pending claims is in error and should be reversed.

If there is any fee due in connection with the filing of this Brief on Appeal, please charge the fee to our Deposit Account No. 50-0925.

Respectfully submitted,

KILYK & BOWERSOX, P.L.L.C.



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APPENDIX

1. A sorbent cartridge comprising at least two layers, wherein one of said layers comprises at least sodium zirconium carbonate in said sorbent cartridge.

2. The sorbent cartridge of claim 1, wherein one of said layers consists essentially of sodium zirconium carbonate.

3. The sorbent cartridge of claim 1, further comprising zirconium phosphate.

4. The sorbent cartridge of claim 3, wherein said zirconium phosphate is present as a layer in said sorbent cartridge.

5. The sorbent cartridge of claim 3, wherein said zirconium phosphate comprises a H^+ content of from about 1.4 to about 2.0 wt%;

a Na^+ content of from about 4 to about 6 wt%;

a ZrO_2 wt% of from about 34 wt% to about 37 wt%;

a PO_4 wt% of from about 41 wt% to about 43 wt%; and

a H_2O wt% of from about 14 wt% to about 18 wt%, based on the weight of the zirconium phosphate.

6. The sorbent cartridge of claim 3, wherein said zirconium phosphate has at least one of the following characteristics:

a) an adsorption capacity for ammonia of from about 20 mg NH_4-N/gm ZrP to about 45 mg NH_4-N/gm ZrP;

an adsorption capacity for Ca^{2+} of from about 2 mEq Ca^{2+}/gm ZrP to about 7 mEq Ca^{2+}/gm ZrP;

an adsorption capacity for Mg^{2+} of from about 1 mEq Mg^{2+}/gm ZrP to about 5 mEq Mg^{2+}/gm ZrP; and

an adsorption capacity for toxic heavy metals of from about 3 mEq HM/gm ZrP to about 9 mEq HM/gm ZrP;

b) a Na^+ content of from about 1.8 mEq Na^+/gm ZrP to about 3 mEq Na^+/gm ZrP at a pH of from about 5.5 to about 6;

c) a minimum leachable PO_4^{3-} of less than about 0.05 mg PO_4^{3-}/gm ZrP; or

d) satisfying ANSI/AAMI RD-5-1992 standard on extractable toxic impurities.

7. The sorbent cartridge of claim 5, wherein said zirconium phosphate has no residual sulfate or chloride.

8. The sorbent cartridge of claim 5, wherein said zirconium phosphate has less than 0.01% sulfate, chloride, or both.

9. The sorbent cartridge of claim 3, wherein said zirconium phosphate in H_2O has a pH of from about 6 to about 7.

10. The sorbent cartridge of claim 3, wherein said zirconium phosphate has an average grain size of from about 30 to about 40 microns.

11. A sorbent cartridge comprising an alkali metal-Group IV B metal carbonate, wherein said alkali metal-Group IV B metal carbonate is present as a layer in said sorbent cartridge.

13. The sorbent cartridge of claim 11, further comprising a Group IV B metal phosphate.

14. The sorbent cartridge of claim 1, further comprising alumina, alumina supported urease, granular activated carbon, or combinations thereof.

15. The sorbent cartridge of claim 14, wherein said alumina, alumina supported urease, and granular activated carbon are each present as separate layers in said sorbent

cartridge.

16. The sorbent cartridge of claim 15, wherein said layers have the following order:

a) said sodium zirconium carbonate;

b) a zirconium phosphate;

c) said alumina;

d) said alumina supported urease;

e) said granular activated carbon.

17. The sorbent cartridge of claim 16, wherein said sorbent cartridge further comprises a first filter pad located above and in contact with said sodium zirconium carbonate, a second filter pad is located between and in contact with said alumina supported urease and said granular activated carbon, and a third filter pad is located beneath and in contact with said granular activated carbon.

18. The sorbent cartridge of claim 17, further comprising a flow diffuser located beneath and in contact with said third filter pad.

19. The sorbent cartridge of claim 1, wherein said sodium zirconium carbonate comprises from about 2 wt% to about 5 wt% Na^+;

from about 44 wt% to about 50 wt% ZrO_2;

from about 12 wt% to about 18 wt% CO_3^{2-}; and

from about 30 wt% to about 40 wt% LOD, based on the weight of the sodium zirconium carbonate.

20. The sodium zirconium carbonate of claim 1, wherein said sodium zirconium carbonate satisfies ANSI/AAMI RD-5-1992 standard on extractable toxic impurities.

21. The sodium zirconium carbonate of claim 1, wherein said sodium zirconium

carbonate satisfies at least one of the following characteristics:

a phosphate adsorption having a minimum capacity of from about 30 to about 35 mg/PO_4-P/gm SZC;

a minimum HCO_3^- content of from about 2 to about 4 mEq HCO_3^- per gm SZC;

a leachable Na^+ content of from about 1.5 to about 2.0 mEq Na^+/gm SZC;

or a pH range of titrated sodium zirconium carbonate of from about 6 to about 7.

22. The sorbent cartridge of claim 1, further comprising hydrous zirconium oxide.

23. The sorbent cartridge of claim 22, wherein said hydrous zirconium oxide is in the acetate form.

24. The sorbent cartridge of claim 23, wherein said sodium zirconium carbonate and said hydrous zirconium oxide are present in a weight ratio of about 1 to 1.

25. The sorbent cartridge of claim 23, wherein said sodium zirconium carbonate and said hydrous zirconium oxide are present in a same layer and are blended together.

26. The sorbent cartridge of claim 1, further comprising zirconium basic carbonate.

27. The sorbent cartridge of claim 26, wherein said zirconium basic carbonate comprises Na^+ of less than about 1000 ppm;

a ZrO_2 wt% of from about 35 wt% to about 40 wt%;

and a CO_3^{2-} of from about 8 wt% to about 10 wt%, based on the weight of the zirconium basic carbonate.

28. The sorbent cartridge of claim 27, wherein said zirconium basic carbonate has about 0 wt% SO_4^{2-} and about 0 wt% Cl^-.

29. The sorbent cartridge of claim 1, wherein said sodium zirconium carbonate is present in said cartridge in an amount of from about 100 grams to about 300 grams.

30. The sorbent cartridge of claim 29, wherein said cartridge further comprises zirconium phosphate in an amount of from about 300 grams to about 1900 grams.

31. The sorbent cartridge of claim 30, further comprising alumina in the amount of from about 100 grams to about 500 grams, immobilized enzyme in an amount of from about 100 grams to about 300 grams, and activated carbon or other adsorbent in an amount of from about 100 grams to about 500 grams.

32. The sorbent cartridge of claim 1, further comprising an immobilized enzyme material capable of enzymatic conversion of urea to ammonium carbonate, a cation exchange material in the sodium or hydrogen form, an anion exchange material in the Ac^-, HCO_3^-, Cl^-, or OH^- form, and an adsorbent capable of removing creatinine, uric acid, or both.

33. The sorbent cartridge of claim 32, further comprising a chlorine removal material.

34. The sorbent cartridge of claim 32, wherein the materials are present as two or more layers in said cartridge.

35. The sorbent cartridge of claim 33, wherein the materials are present as two or more layers in said cartridge.

36. The sorbent cartridge of claim 11, further comprising an immobilized enzyme material capable of enzymatic conversion of urea to ammonium carbonate, a cation exchange material in the sodium or hydrogen form, an anion exchange material in the Ac^-, HCO_3^-, Cl^-, or OH^- form, and an adsorbent capable of removing creatinine, uric acid, or

both.

37. The sorbent cartridge of claim 11, further comprising a chlorine removal material.

38. The sorbent cartridge of claim 11, wherein the materials are present as two or more layers in said cartridge.

40. A method to regenerate or purify spent dialysis fluid comprising passing said spent dialysis fluid through the sorbent cartridge of claim 1.

42. A method to regenerate or purify spent dialysis fluid comprising passing said spent dialysis fluid through the sorbent cartridge of claim 3.

43. A method to regenerate or purify spent dialysis fluid comprising passing said spent dialysis fluid through the sorbent cartridge of claim 4.

44. A method to regenerate or purify spent dialysis fluid comprising passing said spent dialysis fluid through the sorbent cartridge of claim 5.

45. A method to regenerate or purify spent dialysis fluid comprising passing said spent dialysis fluid through the sorbent cartridge of claim 6.

46. A method to regenerate or purify spent dialysis fluid comprising passing said spent dialysis fluid through the sorbent cartridge of claim 11.

48. A method to regenerate or purify spent dialysis fluid comprising passing said spent dialysis fluid through the sorbent cartridge of claim 13.

49. A method to regenerate or purify spent dialysis fluid comprising passing said spent dialysis fluid through the sorbent cartridge of claim 16.

50. An apparatus for conducting dialysis comprising the sorbent cartridge of claim 1, a dialyzer in fluid communication with said cartridge wherein spent dialysis fluid passes

from said dialyzer to and through said cartridge.

51. The apparatus of claim 50, wherein said spent dialysis fluid is spent hemodialysis fluid.

52. The apparatus of claim 50, wherein spent dialysis fluid is restored to original balance of Na^+ and HCO_3^- contents found in fresh dialysate.

53. The apparatus of claim 50, wherein said dialyzer is in fluid communication with the blood of a patient.

54. The apparatus of claim 53, wherein the Na^+ and HCO_3^- balance in said blood is restored to levels found in healthy patient without renal problems.

55. The apparatus of claim 50, wherein said spent dialysis fluid is spent dialysate fluid obtained from a dialyzer wherein spent peritoneal dialysis fluid is passed through said dialyzer and cleaned by fresh dialysate fluid.

56. A dialysis system comprising the sorbent cartridge of claim 1 and a source of spent peritoneal dialysis solution, wherein the source of said spent peritoneal dialysis solution is in fluid communication with said cartridge wherein said spent peritoneal dialysis solution passes to and through said cartridge.

57. The sorbent cartridge of claim 1, wherein said cartridge is capable of restoring the balance of Na^+ and HCO_3^- in spent dialysate to levels found in fresh dialysate.

58. The sorbent cartridge of claim 5, wherein said cartridge is capable of restoring the balance of Na^+ and HCO_3^- in spent dialysate to levels found in fresh dialysate.

59. The sorbent cartridge of claim 31, wherein said cartridge is capable of restoring the balance of Na^+ and HCO_3^- in spent dialysate to levels found in fresh dialysate.

60. The sorbent cartridge of claim 3, wherein said zirconium phosphate is further

away from an inlet opening of said sorbent cartridge than said layer of sodium zirconium carbonate.

61. The sorbent cartridge of claim 4, wherein said layer of zirconium phosphate is further away from an inlet opening of said sorbent cartridge than said layer of sodium zirconium carbonate.